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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,132	02/13/2004	Saburo Kawaguchi	06082.0030	3812
22852	7590	10/17/2006	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			EMCH, GREGORY S	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,132	<b>Applicant(s)</b> KAWAGUCHI ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 5-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/13/04; 3/17/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I, claims 1-4, in the reply filed 21 September 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4 are under examination in the instant office action.

### ***Information Disclosure Statement***

Signed and initialed copies of the IDS papers filed 13 February 2004 and 17 March 2004 are enclosed in this action.

### ***Specification***

The disclosure is objected to because of the following informalities: The specification appears to be a literal translation into English from a foreign document and is replete with grammatical and idiomatic errors. See for example, p.1, lines 16-20 and p.5, lines 19-20.

Appropriate corrections are required.

### ***Claim Objections***

Claims 1-4 are objected to because of the following informalities: Claim 1 recites the typo, "including mainly type-2 astrocytes progenitors". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "mainly" in claim 1 is a relative term, which renders the claim indefinite. The term "mainly" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S.

Patent No. 5,750,376 to Weiss et al.

The claims are directed to a therapeutic agent for curing injured spinal cord, comprising as active ingredients glial cells including mainly type-2 astrocytes progenitors.

U.S. Patent No. 5,750,376 to Weiss et al. discloses generating mixed cultures of O-2A progenitor cells (type-2 astrocyte progenitors) from the spinal cord for transplantation into injured spinal cord for curing the demyelinating lesion (col.11, lines 1-25; col.12, line 43 – col.14, line 3; col.26, line 2 col. 64, line 29 – col.66), thus meeting the limitations of claims 1 and 2. The Weiss et al. patent also discloses that the glial progenitors are for transplantation into a heterologous, autologous or xenogeneic host (col.13, lines 23-24), thus meeting the limitations of claim 3. The Weiss et al. patent also discloses that the cells are suspended at a density of 50,000 cells/ $\mu$ l (col.43, line 49), thus meeting the limitations of claim 4.

Since the patent discloses all the elements of the claims, claims 1-4 are anticipated by U.S. Patent No. 5,750,376 to Weiss et al.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Groves et al. (Nature. 1993 Apr 1;362(6419):453-5; cited on 13 February 2004).

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The claims are directed to a therapeutic agent for curing injured spinal cord, comprising as active ingredients glial cells including mainly type-2 astrocytes progenitors.

Accordingly, the Groves et al. reference teaches generating mixed cultures of rat O-2A progenitor cells (type-2 astrocyte progenitors) and suspending said cells at a density of  $6 \times 10^4$  cells/ $\mu$ l for injection into injured spinal cord (abstract and p.455, paragraph 2), thus meeting the limitations of claims 1 and 4. The Groves et al. reference also teaches that the glial progenitors injected into the spinal lesions are allogeneic (p.455, paragraph 2), thus meeting the limitations of claim 3.

Since the reference teaches all the elements of the claims, claims 1, 3 and 4 are anticipated by Groves et al.

### ***Conclusion***

No claims are allowed.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory S. Emch, Ph.D.  
Patent Examiner  
Art Unit 1649  
10 October 2006



JANET L. ANDRES  
SUPERVISORY PATENT EXAMINER